

**STUDII CLINICE INSTITUTUL ONCOLOGIC "PROF. DR. IOCN CHIRICUȚĂ"**

Nr.	Investigator principal	Nume studiu	Perioada de desfasurare	Localizare	Status
1	Dr. Ciuleanu Tudor	ACCOVION, PM 0259 CA232 J1; Studiu de faza II, randomizat, pentru compararea vinorelbinei orale ca agent unic administrata in doua scheme de tratament la pacienti cu cancer pulmonar avansat cu celule non-mici cu contraindicatie pentru chimioterapia pe baza de platina	aprilie 2015-octombrie 2017	Bronhopulmonar	ongoing
4	Dr. Ciuleanu Tudor	CF102-201HCC A phase 2, Randomized, Double Blind , Placebo-Controlled Study of the Efficacy and Safety of CF102 in the second-line treatment of Advanced Hepatocellular Carcinoma in Subjects with Child- Pugh Class B Cirrhosis	martie 2016- decembrie 2017	Hepatocarcinom	ongoing
7	1.Dr. Ciuleanu Tudor    2. Dr. Cebotaru Cristina	9785-CL-0335 Studiu multinational, de faza 3, randomizat, dublu-orb, controlat placebo, privind eficacitatea si siguranta enzalutamidei in combinatie cu ADT la pacienti cu cancer de prostata metastatic hormono-sensibil	martie 2016- septembrie 2020	Prostata	ongoing

9	1.Dr. Ciuleanu Tudor 2.Dr.Carmen Floares 3. Dr. Cebotaru Cristina	PM1183-C-003-14 Un studiu clinic de faza III, randomizat, efectuat cu lurbinectedina/doxorubicina comparativ cu ciclofosfamida, doxorubicina si vincristin (CAV) sau topotecan ca tratament la pacienti cu cancer pulmonar microcelular (CPMC) care au prezentat esec la o linie anterioara de tratament pe baza de platina (studiul ATLANTIS)	sept 2016-decembrie 2020	Bronhopulmonar	ongoing
15	Dr.Emilia Mihut	Studiu deschis, randomizat, controlat activ, multicentric, de evaluare a eficientei farmacocineticii/ farmacodinamicii, sigurantei, tolerabilitatii si imunogenicitatii administrarii lipefilgrastrim 100 microg/kg greutate corporala in comparatie cu 5 microg/kg de tofilgrastim la copii si adolescenti diagnosticati cu tumori din familia EWING sau rabdomiosarcoame care primesc chimioterapie	mai 2015- iulie 2017	Rabdomiosarcom/ Sarcom EWING	ongoing

16	Dr.Emilia Mihut	Registru european observational colectand date privind eficacitatea cazurilor nou diagnosticate de Leucemie acuta limfoblastica cu Cromozom Philadelphia pozitiv, tratati cu chimioterapie + Imatinib sau transplant de celule stem	aprilie 2014-dec 2020	Leucemie acuta limfoblastica cu Cromozom Philadelphia pozitiv	ongoing
19	Dr.Daniela Grecea	GO29058;A phase III, double blind, placebo-controlled, randomized study of taselisib plus fulvestrant versus placebo plus filvestrant in postmenopausal women with estrogen receptor-positive and her2 negative locally advanced or metastatic breast cancer who have disese recurrence or progression during or after aromatase inhibitor therapy	mai 2015-noiembrie 2018	Mamar	ongoing
20	Dr. Andrada Parvu	CT-P10 3.4; Studiu de faza 3, randomizat, dublu orb, cu grupuri paralele, controlat activ, pentru a compara eficacitatea si siguranta intre CT-P10 si Rituxan la pacientii cu limfom folicular cu incarcatura tumorală redusa	decembrie 2015-decembrie 2019	Limfom folicular	ongoing

23	Dr. Alina Muntean	EMR100070-007; A phase III open label multicenter trial of avelumab (MSB0010718C) versus continuation of first -line chemotherapy in subjects with unresectable, locally advanced or metastatic adenocarcinoma of the stomach or of the gastroesophageal junction	iulie 2015- martie 2018	Gastric	ongoing
24	Dr. Alina Muntean	A Phase III, Open-label, Multicenter Trial of Avelumab (MSB0010718C) Versus Platinum-based Doublet as a First-line Treatment of Recurrent or Stage IV PD-L1+ Non-small Cell Lung Cancer	Octombrie 2016 - Ianuarie 2018	Bronhopulmonar	ongoing
26	Dr.Floares Carmen	um la paciente cu carcinom ovaria	ongoing	Ovar/ Trompe uterine/Peritoneal primar	ongoing
27	Dr.Floares Carmen	a paciente cu carcinom ovarian sau	ongoing	Ovar/ Trompe uterine/Peritoneal primar	ongoing
28	Dr. Cristina Cebotaru	Un studiu multinational, randomizat, dublu-orb, controlat cu placebo , de faza III privind eficacitatea si siguranta ODM-201 la barbatii cu cc de prostata cu risc crescut , nemetastatic, rezistent la castarare	decembrie 2015-decembrie 2020	Prostata	ongoing

29	Dr. Cristina Cebotaru	A randomized, double blind Placebo Controlled Phase 3 study of JNJ-56021927 in subjects with high risk, localized or locally advanced prostate cancer receiving treatment with primary radiation therapy	dec 2015-dec 2025	Prostata	ongoing
32	Dr. Cristina Cebotaru	A Phase 2, Two-Arm Multicenter, Open-Label Study to Determine the Efficacy and the Safety to Two Different Dose Regimens of a pan-FGFR Tyrosine Kinase inhibitor JNJ-42756493 in Subjects with Metastatic or Surgically Unresectable Urothelial Cancer with FGFR Genomic Alterations	ongoing	Carcinom urotelial	ongoing
33	Dr. Tudor Ciuleanu	Juniper : A randomized Phase III study of Abemaciclib plus Best suportiv care vs Erlotinib + best suportiv care in Patients with stage IV NSCLC with Kras mutation who have progressed after platinum based chemotherapy	2015 -deschis pt randomizare	Bronhopulmonar	ongoing

34	Dr. Tudor Ciuleanu	A phase III Randomized ,Open-Labeled ,Multi-Center ,Global study of MEDI4736 monotherapy and MEDI4736 in Combination with Tremelimumab vs standard of care Therapy in Patients with recurrent or metastatic squamos Cell Carcinoma of the head and Neck	2016- deschis pt randomizare	Cap si gat	ongoing
35	Dr. Tudor Ciuleanu	A phase III, double- blind, randomized, placebo-controlled study of PF-05280586 versus Rituximab for the first line treatment of patients with CD20+, low tumor burden follicular lymphoma	2015- continua	Limfom follicular	ongoing
40	Dr. Herghea Delia	Evaluarea incidentei infectiilor cu Clostridium Difficile la pacientii spitalizati sub tratament cu antibiotice (ANTICIPATE) V2.0 din 21 Iulie 2016	martie 2017- mai 2017	Infectii Clostridium Difficile	ongoing
2	Dr. Ciuleanu Tudor	PR-30-5017-C, studiu de faza 3, randomizat, multicentric, dublu-orb, controlat cu placebo, cu medicamentul de investigatie clinica Niraparib ca tratament de mentinere la pacientele cu cancer ovarian avansat, in urma raspunsului la chimioterapia de prima linie pe baza de saruri de platina.	februarie 2017- aprilie 2020	Ovar	pending

3	Dr. Ciuleanu Tudor	GO29431 Studiu de faza 3, deschis, randomizat pentru evaluarea Atezolizumab comparativ cu administrarea unui agent pe baza de platina (cisplatin sau carboplatin) in combinatie cu pemetrexed sau gemcitabina, pacientilor cu cancer pulmonar non-microcelular non-scuamos sau scuamos in stadiul IV, cu PD-L1 exprimat si care nu au primit anterior chimioterapie.	decembrie 2016- decembrie 2020	Bronhopulmonar	pending
5	1.Dr. Ciuleanu Tudor 2.Dr.Carmen Floares 3. Dr.Cebotaru Cristina	NC-6004 (nanoparticule de cisplatina) plus gemcitabina la pacientii cu tumori solide in stadiu avansat sau cancer pulmonar nonmicroceluler scuamos, cancer al cailor biliare si cancer al vezicii urinare	01 iulie 2016-31 decembrie 2019	Bronhopulmonar/Vezica urinara/Cai biliare	pending

6	1.Dr. Ciuleanu Tudor 2. Dr. Cebotaru Cristina	AB12003 Studiu prospectiv, multicentric, randomizat, dublu- orb, placebo-controlat, cu 2 grupuri paralele de faza 3, care compara eficacitatea si siguranta masitinib in combinatie cu docetaxel vs placebo in combinatie cu docetaxel in tratamentul de prima linie in cancerul de prostata hormono- rezistent metastatic (mCRPC)	2015-2019	Prostata	pending
8	Dr. Ciuleanu Tudor	E7080-G000-211 Un studiu de faza II, multicentric, randomizat, dublu orb, cu Lenvatinib (E7080) pentru subiectii cu cancer tiroidian diferentiat, refractar la I131, pentru a evalua daca o doza orala initiala de 21 mg sau 14mg administrat zilnic poate oferi o eficacitate comparabila cu cea data de doza initiala de 24mg, asigurand un profil de siguranta mai bun	sept 2016-mai 2019	Tiroida	pending



10	1.Dr. Ciuleanu Tudor 2. Dr. Cebotaru Cristina	NC-6004-008- Studiu de faza I/II cu administrarea de NC-6004 in combinatie cu 5-FU si Cetuximab ca tratament de prima linie la pacienti cu carcinom cu celule scuamoase recurent metastatic la nivelul capului si gatului.	septembrie 2016- decembrie 2019	Cap si gat	pending
11	Dr. Ciuleanu Tudor	B9991003- Studiu de faza 3, multinational, randomizat, deschis, cu brate paralele, pentru evaluarea Avelumab in asociere cu Axitinib comparativ cu monoterapia cu Sunitinib ca tratament de prima linie la pacienti cu carcinom reno-celular avansat	sept 2015- iulie 2021	Renal	pending
12	Dr. Ciuleanu Tudor	CA209-743; A phase III, randomized, open label trial of Nivolumab in combination with Ipilimumab versus Pemetrexed with Cisplatin or Carboplatin as first Therapy in unresectable Pleural Mesothelioma.	mai 2017- octombrie 2021	Mezoteliom pleural	pending

13	Dr. Ciuleanu Tudor	CA209-451 A randomized, multicenter, double-blind, phase 3 study of Nivolumab, Nivolumab in combination with Ipilimumab, or placebo in subjects with extensive-stage disease small cell lung cancer (ED-SCLC) after completion of Platinum-based first line	ianuarie 2017-septembrie 2019	Bronhopulmonar	pending
14	Dr. Ciuleanu Tudor	CA209-816 Randomized, Open-Label, Phase 3 Trial of Nivolumab and Ipilimumab versus Platinum-Doublet Chemotherapy in Early Stage NSCLC	septembrie 2017-ianuarie 2024	Bronhopulmonar	pending
17	Dr. Alexandru Eniu	ACCOVION, PM 0259 CA233 B0; Studiu randomizat de faza II care compara, drept chimioterapie de prima linie, vinorelbina orala ca agent unic administrate cu doua scheme de tratament duferite la pacienti cu cancer de san avansat.	aprilie 2015-octombrie 2017	Mamar	pending

18	Dr. Alexandru Eniu	Solar I (CBL719C2301); Studiu de faza III, randomizat, in regim dublu-orb , controlat cu placebo, privind aleplisib in combinatie cu fulvestrant pentru barbati si pentru femeile dupa varsta menopauzei si diagnosticate cu cancer mamar in stadiu avansat, pozitiv pentru receptorii hormonal si cu Her2 negativ, care a avansat in timpul tratamnetului ci inhibitori de aromataza (IA) sau dupa aceasta	01 ian 2016-01 iunie 2018	Mamar	pending
21	Dr.Ljubomir Petrov; Dr. Laura Urian	GS-US-313-1580 Dose optimization study of Idealisib in follicular lymphoma and small lymphocytic lymphoma	2015-2021	Limfom folicular	pending
22	Dr. Andrada Parvu	ACE-CL-309; Un studiu de faza 3, multicentric, randomizat, in regim deschis, privind acalabrutinib (ACP-196) comparativ cu terapia aleasa de investigator, fie idelalisib plus rituximab, fie bendamustina plus rituximab, la subiecti cu leucemie limfocitara cronica recidivanta sau refractara.	august 2016- decembrie 2020	Leucemie limfocitara cronica	pending

25	Dr. Alina Muntean	A Randomised, Parallel, Double Blinded Study to Compare the Efficacy and Safety of FKB238 to Avastin® In 1st Line Treatment for Patients With Advanced/Recurrent Non Squamous NSCLC in Combination of Paclitaxel and Carboplatin	Pending	Bronhopulmonar	pending
30	Dr. Cristina Cebotaru	Protocol LSK-AM301, A prospective, randomized, double-blind, placebo-controlled, multinational, multicenter, parallel-group, phase III study to evaluate the efficacy and safety of Apatinib plus BSC compared to placebo plus BSC in patients with advanced or metastatic gastric cancer.	decembrie 2016-mai 2019	Gastric	pending
31	Dr. Cristina Cebotaru	SAUL-MO29983; Studiu multicentric deschis, cu un singur brat, de evaluare a sigurantei Atezolizumab in tratarea carcinomului urotelial si non-urotelial al tractului urinar, avansat local sau metastatic.	ianuarie 2017- februarie 2023	Renal	pending

36	1.Dr. Ciuleanu Tudor 2. Dr. Cebotaru Cristina	AB 12008 A prospective, multicenter, open-label, centrally allocated, active-controlled, phase 2/3 study to evaluate the efficacy and safety of masitinib in combination with gemcitabine versus gemcitabine alone in advanced/metastatic epithelial ovarian cancer patients in second line being refractory to first line platinum treatment or in third line.	aprilie 2017-aprilie 2020	Ovar	pending
37	Dr. Andrada Parvu	BAY 80-6946/ 17067 CHRONOS-3 A phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of copanlisib in combination with rituximab in patients with relapsed indolent B-cell non-Hodgkin's lymphoma (iNHL)-CHRONOS-3	iulie 2016-decembrie 2020	Indolent B-cell non-Hodgkin's lymphoma	pending

38	Dr. Ciuleanu Tudor	CA209-817 Studiu de faza III/IV de evaluare a sigurantei administrarii nivolumab in doza fixa in asociere cu ipilimumab la pacienti cu diagnostic de cancer pulmonar fara celule mici	mai 2017- octombrie 2021	Bronhopulmonar	pending
39	Dr. Anca Vasilache	20160275 A randomized, open-label, phase 3 study comparing Carfilzomib, dexamethazone, and Daratumumab to Carfilzomib and dexamethazone for the treatment of patients with relapsed or refractory multiple myeloma.	2017-2019	Mielom multiplu	pending